

## TCT-429

**Short- and intermediate- term clinical outcomes after implantation of everolimus-eluting bioresorbable scaffold in complex lesions : a prospective single-arm study - ABSORB Expand trial**

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**Background:** Bioresorbable scaffold is a novel approach that provides transient vessel support with drug delivery capability without the long-term limitations of metallic drug-eluting stents. The everolimus-eluting bioresorbable scaffold (ABSORB; Abbott vascular, CA, USA) has been shown to be effective in the context of first-in-man trials including simple lesion(s). However, the effect of ABSORB implantation in more complex patients cannot be directly extrapolated from these findings. We sought to evaluate the impact of this novel technology on the short- and intermediate- term clinical outcomes in a real-life population with complex lesions.

**Methods:** Since September 1st 2013, our institution commenced the use of ABSORB scaffold in patients with complex lesions including a long lesion (>32mm in length), a calcified lesion, a bifurcation lesion and a large vessel with up to 4mm in diameter. Patients presenting with stable angina, unstable angina and non-ST elevation myocardial infarction were included. In total 300 patients presenting with de novo complex lesions will be treated exclusively with ABSORB scaffolds.

**Results:** Up to May 1, 2013, 137 patients were included in the study. In total 248 scaffolds were implanted, with a procedural success rate of 95%, in the lesions including 40 bifurcations and 11 chronic total occlusions. In 52 patients (53 lesions), more than one scaffold was implanted with overlap. An interim analysis of the population at one month revealed no MACE event except for one myocardial infarction. The enrolment is ongoing while the updated one-month and 6-month data on the occurrence of death, MI, repeat revascularization and scaffold thrombosis are currently being collected and will be presented at the time of the meeting. Survival information will be obtained from municipal civil registries.

**Conclusions:** The short-term and intermediate-term clinical safety and efficacy of the ABSORB scaffold in complex lesions will be presented at the meeting.

## TCT-430

**ABSORB everolimus-eluting bioresorbable vascular scaffold (BVS) implantation in daily clinical practice. A single center registry analysis**

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**Background:** The ABSORB™ bioresorbable vascular scaffold (BVS) (Abbott Vascular, Santa Clara, CA, USA) is a resorbable polymeric scaffold that provides temporary scaffolding and everolimus drug delivery. The resorption of the BVS potentially overcomes the limitations of metallic stents. There is limited data on its use in daily clinical practice, especially in acute coronary syndrome (ACS) patients and complex lesions. We assessed the safety and performance of ABSORB BVS implantation in a selected patient cohort comparable with "real world" situation.

**Methods:** All patients who had undergone percutaneous coronary intervention (PCI) with ABSORB BVS implantation in our centre between August 2012 and June 2013 were included in this registry. Clinical outcome were defined as cardiac death, myocardial infarction (MI), target vessel revascularization (TVR), target lesion revascularization (TLR), scaffold thrombosis (ST), and major adverse cardiac event (MACE; composite of cardiac death, MI and TVR). In addition, Quantitative Coronary Analysis including angiographic success rate will be performed and available at TCT.

**Results:** A total of 117 patients (136 lesions) were treated with an ABSORB BVS. The indication for PCI was stable angina in 53 patients (45%), non ST-segment elevation acute coronary syndrome (NSTEMI) in 38 patients (33%), and ST-segment elevation myocardial infarction (STEMI), in the setting of primary PCI, in 20 patients (17%). In total 64% of the 136 lesions had type B2 or C ACC/AHA classification, including 9 chronic total occlusions, 2 left main, 4 ostial, 3 long (>50 mm) and 8 complex bifurcation lesions treated with Tryton bifurcation stent and BVS. At least 1 month follow-up was available in 94 patients (median follow up 54 days; Q1-Q3: 40-67). MACE occurred in 4 patients (4.2%). Two patients experienced MI due to subacute scaffold thrombosis and two patients needed target vessel revascularization, including one target lesion, due to recurrent angina pectoris.

**Conclusions:** In a patient population reflecting daily clinical practice, including high-risk lesions and high-risk patients, the ABSORB BVS had good short term results.

## TCT-431

**Angiographic Results of a novel Novolimus Eluting Bioresorbable Coronary Scaffold System (NEBCSS) for the treatment of single de-novo coronary artery lesions: 6 month Serial QCA analysis results from the pivotal, prospective, multicentre, DESolve NX Trial**

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**Background:** By design, drug-eluting bioresorbable scaffolds have been developed as an alternative to metallic stents in order to provide temporary vascular scaffolding, prevent vessel recoil and inhibit late clinical events due to excessive neointimal hyperplasia formation including restenosis and lesion revascularization. The DESolve® bioresorbable scaffold (Elixir Medical Co., Sunnyvale, CA) is a novel device combining a PLLA-based scaffold coated with a bioresorbable polylactide-based polymer and a potent anti-proliferative sirolimus metabolite Novolimus, with a drug dose of 5 mcg per mm of scaffold length. Our objective was to report serial QCA results from the prospective, non-randomized, single-arm multicentre DESolve NX trial.

**Methods:** A total of 126 patients/lesions were enrolled in 13 sites in Europe, New Zealand and Brazil. Lesion criteria were single de novo lesion <14 mm in length, located in native coronary vessels 2.75-3.50 mm in diameter, with stenosis between 50-90% and TIMI flow ≥2. The study device was available in 3.00, 3.25 and 3.50 mm in diameter and 14 and 18 mm in length. All patients were assigned to angiographic follow-up at 6 months. Quantitative coronary angiography (QCA) analysis was performed at an independent angiographic core laboratory.

**Results:** Overall, mean age was 62 years and 21% had diabetes. Target lesions were evenly distributed in LAD, LCx and RCA, and most lesions were classified as type B (71%) according to the ACC/AHA classification. During procedure, the study device was successfully implanted in 122/126 cases (97%). Serial QCA results are shown in the Table.

Variable	Preprocedure	Postprocedure*	6-Month Follow-up*
N	126	126	113
Lesion length, mm	11.20±3.77	-	-
Reference diameter, mm	3.06±0.31	3.09±0.26	3.01±0.29
MLD, mm	0.92±0.40	2.67±0.28	2.45±0.44
% DS	69.9±12.3	13.5±7.8	18.3±13.6
Acute gain, mm	-	1.73±0.45	-
% acute recoil, mm	-	6.6±6.2	-
Late lumen loss, mm	-	-	0.21±0.34
*In-scaffold			

**Conclusions:** Angiographic results of the novel DESolve bioresorbable scaffold showed promising results in de novo coronary artery lesions including relatively low in-scaffold late lumen loss, a surrogate of neointimal hyperplasia, at 6-month follow-up.

## TCT-432

**Bioresorbable Vascular Scaffolds in Complex Coronary Lesions**

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**Background:** The use of bioresorbable vascular scaffolds (BVS) has largely been restricted to simple lesions with a relatively small number of patients treated with complex lesions. The aim of this study was to evaluate the device success and short-term clinical outcomes of BVS in 'real world' patients including those with complex coronary lesions.

**Methods:** All consecutive patients treated with BVS between May 2012 and June 2013 at 2 centres were included in this analysis.

**Results:** A total of 123 lesions in 82 patients (87.8% male, mean age 64.6 years) were treated with BVS. Complex lesions were distributed as follows: long lesion >20mm (n=83), bifurcation lesions (n=49), calcified lesions (n=42), chronic total occlusions (n=9) and in-stent restenoses (n=7), one feature could be present in more than one lesion. Intracoronary vascular ultrasound and optical computed tomography were used in 85.4% and 20.3% of cases, respectively. Pre-dilation was performed in 98.4%, while post-dilation (mean 21.5 atmosphere) was utilized in all cases. Rotablation or scoring balloon was used in 22.0%. Device success was achieved in 99.2%. At median follow-up of 147

days, there were no death, follow-up myocardial infarction or stent thrombosis. There was however 1 case of target vessel revascularization not related to BVS.

**Conclusions:** These preliminary results suggest that complex lesions can possibly be successfully treated with BVS. Intravascular ultrasound guidance and meticulous technique may be important to optimize clinical outcomes.

## Circulatory Support, Heart Failure, and HOCM

*Moscone West, 1st Floor*

**Tuesday, October 29, 2013, 3:30 PM–5:30 PM**

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### TCT-433

#### Percutaneous coronary intervention with a percutaneous left ventricular assist device support (TandemHeart®): 6 years' experience and outcomes

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**Background:** We have used the TandemHeart® (Cardiac Assist, Pittsburgh, PA) percutaneous left ventricular assist device during percutaneous coronary intervention (PCI) in patients for whom conventional PCI and aorto-coronary bypass would pose substantial risk due to comorbidities and/or clinical presentation. We present a retrospective series of patients and report clinical outcomes with a 6 year follow up

**Methods:** We retrospectively analyzed data from 626 consecutive PCIs at the Texas Heart Institute from 2005 to 2011. Among these, we identified 74 cases performed with TandemHeart support. Cases were classified as elective, urgent, emergent, or emergent salvage according to STS definitions. To standardize intervention's complexity, we calculated each patient's SYNTAX score. Ejection fraction prior to the procedure (EF), left mean atrial pressure prior to PCI (LAP), mean cardiac output provided by mechanical support (mCO) and length of hemodynamic support provided for successful weaning (LCS) were recorded. Incidences of 30-day mortality, prolonged hospital stay (i.e. hospitalization greater than 14 days), stroke, prolonged ventilation (i.e. > 24 hours), post-procedural acute kidney injury (i.e. increase of greater than 0.5 mg/dl in creatinine).

**Results:** Mortality at 30 days for the elective, urgent, emergent, and emergent salvage subgroups was 6%, 12%, 22%, and 38%. Anatomic complexity (SYNTAX score), hemodynamic instability (LAP) and morbidity were collected for each group. In the elective subgroup LCS was 1±0.1 days and all patients in this group were successfully weaned from mechanical support. In the urgent subgroup LCS was 3.9±2.6 days and all patients were successfully weaned from mechanical support. In the emergent subgroup LCS was 3.9±2.6 days, and 84% (16/19) patients were successfully weaned from mechanical support. In the rescue subgroup 67% of the patients (14/22) cardiopulmonary resuscitation (CPR) was in progress or had recently performed prior to the procedure, LCS was 6.9±4.5 days and 54% (12/22) patients were successfully weaned.

**Conclusions:** TandemHeart-assisted PCI is a valid option for revascularization in profound cardiogenic shock and extreme-risk elective revascularization.

### TCT-434

#### Effectiveness and Safety Beyond 10 Years of Percutaneous Transluminal Septal Ablation in the Hypertrophic Obstructive Cardiomyopathy: Results from a Multicenter Registry.

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**Background:** Percutaneous transluminal septal ablation (PTSMA) is an alternative treatment to surgery in patients with hypertrophic obstructive cardiomyopathy (HOCM) with advanced symptoms despite optimal medical treatment, specially under high surgical risk. However, due to the relatively new introduction of the technique the very long term results of PTSMA (>10 years) are unknown.

**Methods:** We have included in the present study consecutive patients with HOCM treated with PTSMA in 5 centers between 1998 and 2003. We have analyzed clinical, hemodynamic and echocardiographic data at baseline and follow up.

**Results:** A total of 45 patients were included, 31 (69%) women and mean age 62.4±14 years. Among those 39 (86.6%) were in NYHA class III or IV. The septum thickness was 21.8±3.5 mm, maximum basal gradient in echo 77±39 mmHg and mitral regurgitation

was at least moderate in 22 (48.8%). In hospitalization 3 pts required permanent pacemaker implantation and 1 pt had ventricular perforation (by pacing lead) undergoing surgery. After a median follow up of 12.3 years (11-13.5), 9 pts died and among these 2 pts (4.4%) suffered cardiac death (heart failure and post-transplantation), 2 pts underwent ICD implantation (the case with perforation and surgery due to subsequent ventricular tachycardia, and other for primary prevention), 2 underwent cardiac surgery (endocarditis and severe mitral regurgitation). In the last clinical review NYHA class was I-II in 39 (86.6%), (p<0.0001), the maximum basal gradient was 16±23 mmHg (p<0.0001) and mitral regurgitation was absent or mild in 34 (75.5%) (p<0.03).

**Conclusions:** The results of this study suggest safety and efficacy for PTSMA at a very long term follow up, over 10 years. A sustained reduction in gradients, mitral regurgitation and functional class is observed. This treatment was not associated with significant incidence of sudden death or ventricular arrhythmias.

### TCT-435

#### Early experience of CT angiography in planning alcohol septal ablation (ASA) for hypertrophic obstructive cardiomyopathy (HOCM)

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**Background:** ASA is an established treatment for HOCM. Up to 30% have an unsatisfactory outcome from intended treatment.

**Methods:** CT images are used to highlight the SAM-septal contact point. Vascular supply to this area is identified, the course and origin of these vessels are described. The target septal is labeled and a 3D angiogram created to define optimal angiographic angles. All major epicardial arteries are surveyed to identify any further target vessels and exclude those with an inappropriate distribution.

**Results:** 16 patients have undergone CT angiography prior to ASA. The approach to ASA was changed in 9. CT can identify septal arteries that bifurcate to supply both the left and right ventricular septum. Contrast injection into the ostium of such arteries localises to the RV due to the pressure differential between coronary flow to RV and LV. On balloon occlusion of the LV sub-branch the contrast localises to the target area. CT can reliably determine the sub-branch that supplies the target area. This has occurred in 6/16 patients. 3 patients had epicardial artery source other than LAD (circumflex, diagonal, obtuse marginal). 12 patients have received alcohol and have >1 month review. 11/12 have improved dyspnoea (one has progressive pulmonary fibrosis). LVOT gradients have decreased by >50% from baseline to a final level of <50mmHg in all. Peak VO2 is improved in all 6 who have undergone 6-month testing.

**Conclusions:** CT has the ability to describe intricate details of septal arterial anatomy. Our approach to ASA is changing and contrast localisation is more accurate. Initial results are very encouraging.

